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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/997,449

11/30/2001

Shamim M. Malik

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/997,449	<b>Applicant(s)</b> MALIK ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-10,13 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-10,13 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This action is in response to the applicant's amendment received on 08 September 2008. Claims 2, 3, 7, 11, 12, and 14-30 remain cancelled.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-6, 8-10, 13, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (6,083,257) in view of Ecer et al. (4,486,247), or in the alternative, over Taylor et al. in view of Ecer et al. and Kamath et al. (6,335,029).

Taylor discloses a stent (see entire document) comprising a metallic stent body formed of a stainless steel alloy (for example, see column 5, lines 51-56 and lines 62-63) having a polymer film (for example see column 3, lines 63-67).

Taylor fails to disclose the stent body comprises a carbon deposit. However, it is well known that stainless steel materials containing carbon implanted within the surface

as claimed enhances the strength and hardness of the stainless steel surface. Ecer discloses a stainless steel base material being modified by having carbon implanted within the surface of the stainless steel base material in order to enhance wear resistance (see detailed description of the Ecer et al. patent). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's stent body with a carbon deposit as taught by Ecer. Doing so would improve the stent's wear resistance. To further provide the carbon deposit such that it is present at a depth of not more than about 2000 Å beneath the stent body surface would have been obvious to one having ordinary skill in the art at the time the invention was made, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

The limitation "plasma-polymerized" is being treated as a product by process limitation, in that "plasma-polymerized" refers to the process of depositing the polymer film layer to the stent and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re

Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, a stent as described above wherein the polymer film layer is plasma-polymerized over the stent body is directed to the method of making the stent and not to the final product made. It appears that the product disclosed by Taylor in view of Ecer would be the same or similar as that claimed; especially since both applicant's product and the prior art product have the same final structure of a metallic stent body having a carbon deposit and a polymer film layer.

In the alternative Kamath teaches applying a polymer film to a stent by a plasma polymerization process. Kamath teaches that this process allows covalent bonding between layers, thus subsequently offers a stronger adhesion (for example, see column 8, lines 37-44). It is well within the general knowledge of one having ordinary skill in the art to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to try depositing Taylor's in view of Ecer polymer film layer by a plasma polymerization process as taught by Kamath et al. Doing so would enhance the bond between the stent body and the polymer film. Since the plasma-polymerization process forms chemical bonds, the film layer would be chemically bonded to the stent body, including the carbon deposits.

With further respect to claims 4-6, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the film layer with the materials claimed, since it has been held to be within the general skill of a worker in

the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With further respect to claim 10, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the stent with a polymeric layer comprising a therapeutic substance, since it is well known in the art to coat stents with drugs and agents in order to provide further treatment to the placement site. In the alternative, Kamath teaches forming a polymeric layer comprising a therapeutic substance formed on the plasma-polymerized film layer (see detailed description). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a polymeric layer comprising a therapeutic substance on the polymer film layer as taught by Kamath. Doing so would promote further healing to the treatment site.

### ***Response to Arguments***

Applicant's arguments filed 08 September 2008 have been fully considered but they are not persuasive. The applicant argues primarily that the prior art fails to disclose, teach, or suggest each and every element as claimed. Examiner respectfully disagrees.

The applicant argues primarily that since Kamath discloses a plasma polymerized polymer film applied to another layer that has been applied to the stent body, Kamath fails to disclose polymer coatings applied over a stent body surface. However, Taylor in

view of Ecer discloses a stent body having carbon deposits at a depth beneath the stent body surface and a polymer film deposited directly over the stent body surface (see rejection above). Kamath teaches that the process of depositing polymer films to stents by a plasma polymerization process is well known in the art in order to form chemical bonds between surfaces and thus enhancing bonds between surfaces (see rejection above). Even though Kamath teaches the process between films deposited over a stent body, Taylor in view of Ecer discloses the polymer film is deposited directly over the stent body surface. It is the examiner's position that to try applying the polymer film of Taylor in view of Ecer directly to the stent body surface by plasma-polymerization would have been obvious to one having ordinary skill in the art at the time the invention was made. Doing so may enhance the bond between the stent body surface and polymer film. Regarding the applicant's argument that Taylor and Kamath together make no mention of using carbon deposits in the metal stent for chemical bonding, it is the examiner's position that since plasma-polymerization forms chemical bonds, the process itself would form a chemical bond between the polymer film and stent body, including the carbon deposits, of the stent of Taylor in view of Ecer.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a



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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
November 20, 2008

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773